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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 07/01/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/764,783

Applicant(s)

RODRIGUEZ ET AL.

Examiner

Arun Chakrabarti

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Application/Control Number: 09/764,783

Art Unit: 1634

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 7-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for identifying any change in the body of a human being caused by any physiological or pathological condition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Court in *re Wands*, 8 USPQ2d 1400 (CA FC 1988) stated with regard to enablement that

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

Here, the claim is broadly drawn to a method for identifying any change in the body of a

Art Unit: 1634

human being caused by any physiological or pathological condition. However, the specification does not provide guidance commensurate in scope with this claim; only generically teaches the detection of DNA from pregnant woman, breast cancer and cervical cancer. The specification provides no guidance regarding methods for identification of any other change in the body of a human being caused by any other physiological or pathological condition and no guidance has been provided to detect DNA patterns in male patients. There are only three working examples of such testing with pregnant woman, breast cancer and cervical cancer. It is highly unpredictable whether or what other disease would be detected by identifying DNA extracted from blood. This unpredictability arises from the following facts: (1) DNA patterns even from the same pregnant woman are not reproducible as shown in the Figures 2A-3E of the specification, (2) There is no correlation between the disease or physiological changes and the DNA pattern, (3) There is no S.E.M. value to determine the degree of significance of the DNA pattern (p-value as usually determined by Student's t-test), and (4) Control or normal DNA pattern is lacking in all the experiments which is an essential requirement of studying and comparing the detection of diseases. Thus, given these many unpredictable and, at least in the specification, non reproducible data, no correlation between any specific result has been shown. For example, no correlation between breast cancer and a control nuclear morphology has been shown which properly supports the unpredictability elements discussed above. Without such a correlation, based on proper controls, and statistically significant data, the method will not predictably detect or function to detect any particular disease state. It would require a large amount of

Art Unit: 1634

experimentation, potentially including the processing of blood in several thousands of diseases, physiological abnormalities and pathological conditions, in order to identify additional DNA pattern with the claimed functionality. Given the Wand's factors opposing the full scope of enablement including the limited teaching in the specification, the presence of only pregnant woman, breast cancer and cervical cancer studies without any S.E.M. value to determine the degree of significance (p-value as usually determined by Student's t-test), the teaching of unpredictability in the prior art, the unpredictability of the art, the breadth of the claim, and the large amount of experimentation needed, with only the skill level in the art being neutral towards enablement, it is concluded that undue experimentation is necessary to make and use the invention as broadly claimed. Moreover, the claimed utility of identifying a change in the body of a human being caused by a physiological or pathological condition is not enabled by any supportive evidence provided in the specification.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph because of the lack of written description. With regard to the written description, all of these claims encompass strand pattern of DNA complex which is "approximately circular or polygonal or generally linear or linear in combination with at least one elongated ring or plurality of beads and a substantial discontinuity with associated branching or strand which is not smooth throughout most of the strand's length," for which no written description is provided in the specification except the figures which are drawn by hand and it is not clear from the specification if they are microscopic pictures or derived therefrom or even if derived, how the diagram is obtained. In absence of

Art Unit: 1634

written description of the source of diagrams, it is not clear how the particular shapes of the DNA complex of human blood samples can be correlated to any disease or determining the sex of fetus.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the hand-drawn pictures are shown. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception or written description of any shape of the strand pattern in the claimed method.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 9-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims are rejected over the recitation of the

Art Unit: 1634

phrase, "approximately circular or polygonal or generally linear or linear in combination with at least one elongated ring or plurality of beads and a substantial discontinuity with associated branching or strand which is not smooth throughout most of the strand's length". In absence of any definition of the terms "approximately circular or polygonal or generally linear or linear in combination with at least one elongated ring or plurality of beads and a substantial discontinuity with associated branching or strand which is not smooth throughout most of the strand's length", the claims are vague and indefinite.

The term "approximately circular or polygonal or generally linear or linear in combination with at least one elongated ring or plurality of beads and a substantial discontinuity with associated branching or strand which is not smooth throughout most of the strand's length" in claims are also relative terms which render the claims indefinite. The term "approximately circular or polygonal or generally linear or linear in combination with at least one elongated ring or plurality of beads and a substantial discontinuity with associated branching or strand which is not smooth throughout most of the strand's length" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. .

Response to Amendment

Art Unit: 1634

4. In response to amendment, previous 112 (second paragraph) rejections have been withdrawn. However, new written description and 112 (second paragraph) rejection have been included.

Response to Arguments

5. Applicant's arguments and declaration filed on May 17, 2002 have been fully considered but they are not persuasive.

Applicant mentions in the declaration that 1000 pregnant woman were studied but it is not declared whether any kind of pathological condition has been studied or not, which is deemed to be the special feature of the invention, especially claims 7-20.

Applicant declares that DNA patterns for any given blood sample from the same person exhibited practically identical shapes which is in contrast to the specification (DNA patterns even from the same pregnant woman are not reproducible as shown in the Figures 2A-3E of the specification).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1634

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

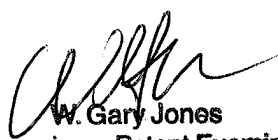
Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Chakrabarti

Patent Examiner

Art Unit 1634

June 19, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600